Standard Imaging®

MAY 11 2004

K040688

March 11, 2004

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| Subject: | 510(k) Summary of Safety and Effectiveness Information for the Standard Imaging e.IMRT Calculator |
| Proprietary Name: | Standard Imaging e.IMRT Calculator |
| Common Name: | Electron Beam Planning Calculator |
| Classification Name: | Medical Charged-Particle Radiation Therapy System, Treatment Planning Computer Program |
| Classification: | Class II – 21CFR892.5050, 90MUJ |
| Panel: | Radiology |
| Contact Person: | Raymond Riddle, Vice President, Regulatory Affairs |

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Standard Imaging e.IMRT Calculator is substantially equivalent to the electron portion of the ADAC Laboratories (Philips) Pinnacle 3 Radiation Therapy Planning Software covered by 510(k) Numbers K951581, K993923, K032724.

The e.IMRT Calculator is a simple, stand-alone software program provided on a CD-rom for use on an appropriately configured personal computer. It is intended to assist the oncologist or medical physicist in creating an optimum electron treatment plan based on the treatment objective for the patient.

Using previously established mathematical equations, the e.IMRT Calculator suggests several potential electron beam treatment energy solutions, within user selected parameters, by combining several discrete energies typically available on the linear accelerator(s). It uses previously user gathered or generated depth dose data sets for each electron energy available (4, 6, 9, 12, 15, 16, 18, 20 or 22 MeV) on the user's specific liner accelerator(s) as its primary input. Other inputs involve the identification of the facility, specific linear accelerator(s) and bolus used.

9


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The output of the e.IMRT calculator is a hardcopy printout of the suggested electron beam treatment energies, in both numeric and graphical formats. The site, linear accelerator and bolus information are also provided on this printout are the site. The e.IMRT Calculator does not, however, electronically store any patient identification data or information. Inputs involving patient information are only used for hardcopy printouts.

Specific electron beam parameters are selected from the solution options provided by the e.IMRT Calculator for non-direct (manual) input into the user's radiation treatment planning system. The treatment planning system then creates a treatment plan based on the treatment objective for the patient, which is reviewed by the attending oncologist for acceptability prior to implementation with a linear accelerator.

The Standard Imaging e.IMRT Calculator was designed to comply with the applicable portions ~~of the following voluntary standard~~:

1. ~~IEC 60601-1-4 (Edition 1.1 2000-04)~~ -- Collateral standard for programmable medical systems

The Standard Imaging e.IMRT Calculator has been validated at Standard Imaging and at the University of Wisconsin – Madison. This validation included the following:

1. Algorithm transfer
2. Results presentation and graphing
3. Absolute dose depth measurements
4. Interface, compatibility, use and misuse
5. Treatment planning system comparison analysis

The Standard Imaging e.IMRT Calculator has met its predetermined design specifications, risk analysis and validation objectives.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2004

Mr. Raymond T. Riddle, PE, RAC
Vice President, Regulatory Affairs
Standard Imaging, Inc.
7601 Murphy Drive
MIDDLETON WI 53562-2532

Re: K040688
Trade/Device Name: Standard Imaging e.IMRT Calculator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle Radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: March 11, 2004
Received: March 16, 2004

Dear Mr. Riddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040688

Indications for Use

510(k) Number (if known): K040688

Device Name: Standard Imaging e.IMRT Calculator

Indications For Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~and~~/or Over-the-Counter-Use ____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040688



8